I: NATURAL HISTORY AND EPIDEMIOLOGY

AREA OF EMPHASIS:

Natural History and Epidemiology

SCIENTIFIC ISSUES

The deployment of effective means of prevention and treatment of HIV/AIDS requires a constant reevaluation of research findings, the testing of new scientific hypotheses, and the incorporation of research results in diverse circumstances and populations.

In the United States and other industrialized countries, after a continuous increase in the 1980s, steep declines in AIDS diagnoses were observed from the mid-1990s through 2001. Such improvements have been mostly attributable to the widespread use of new and effective treatment regimens. In recent years, while the death rate among persons with AIDS has continued to decline, the rate of decline in AIDS diagnoses has slowed down.

The composition of the epidemic in the United States, and in many other industrialized countries, reveals that new HIV infections occur more frequently in racial and ethnic minorities, groups with high-risk sexual behaviors, injecting drug users, and adolescents. The use of potent antiretroviral therapy (ART) has favorably influenced the progression of HIV disease, extending the time between HIV infection and development of AIDS. A more complex pathology, however, is being uncovered as HIV-infected people live longer and develop age-related comorbidities. In addition, undesired effects of ART have been observed. Epidemiologic research has been instrumental in identifying and describing such effects, disentangling effects related to treatment from those related to HIV disease

itself. Since the beginning of the HIV epidemic, NIH-supported epidemiologic research has played a key role in elucidating the interplay of virus, host, and environment.

Worldwide, studies have shown a global spread of a heterogeneous epidemic, mostly fueled by heterosexual transmission and, in some geographic areas, augmented by injecting drug use. ART has the potential to become, for the first time since the beginning of the epidemic, a more frequent backdrop where research on HIV/AIDS is being conducted. Thus, well-designed epidemiological studies will help to characterize local epidemics; the respective effects of viral, host, and environmental factors on HIV transmission and disease progression; and the measurable effects of ART. These studies will serve as the basis for designing rational, evidence-based interventions. The value of traditional research in the epidemiology of HIV/AIDS will increase when complemented by operational research that will define the optimal process of treatment and care to achieve the best outcomes.

PRIORITY FOR FUTURE RESEARCH:

- **Sponsor domestic and international epidemiologic studies to characterize modes of transmission, including host characteristics (e.g., sexual behavior, substance use, use of blood products and other injections, effects of treatment, genetic variation) and viral characteristics (e.g., subtype, viral load, drug resistance, tropism), or continued risk behaviors in HIV-infected and uninfected populations of adults, adolescents, and children.**

Studies of certain HIV transmission modalities, such as mother-to-child transmission (MTCT), have resulted in the use of prevention measures that have led to a dramatically lower level of HIV transmission in the industrialized world. After accounting for situations that are common in the developing world (e.g., the more frequent use of breastfeeding), similar prevention measures, based on various antiretroviral (ARV) drug regimens, are beginning to be applied in developing countries. However, sexual transmission is still the mode of HIV transmission that accounts for most of the global spread of the HIV/AIDS epidemic. As a necessary prerequisite to the development of successful interventions, research efforts must continue to identify the critical biological and behavioral determinants and cofactors that favor transmission of HIV. These efforts include studying how the interplay of host and viral characteristics results in variable degrees of transmission probability. In a setting of rapid and continued evolution of the virus, the monitoring of such viral features as recombination and development of resistance to ARV drugs are critically important to curtail

transmission. Rigorous NIH-sponsored epidemiological studies are needed for the detailed characterization of risk factors for HIV transmission in different populations, including increases in risk behaviors by individuals who receive various types of interventions.

PRIORITY FOR FUTURE RESEARCH:

- **Develop, maintain, and effectively utilize domestic and international cohorts, repositories, and nested studies among populations experiencing emerging and ongoing HIV epidemics to establish databases that support analyses of host and viral characteristics. Use this approach as the basis for the use of integrated databases to:**
  - **Assess the impact of interventions on HIV-related outcomes through the use of operations research;**
  - **Evaluate treatment effectiveness at the individual and population levels; and**
  - **Increase the understanding of the pathogenesis of HIV infection and disease.**

The development and maintenance of a domestic and international infrastructure is necessary for the study of biological and behavioral aspects of HIV/AIDS in new or previously understudied populations. The NIH will continue to emphasize the importance of cohort studies to investigate the rate of HIV disease progression, the causes of death, and the impact of therapy on the changing spectrum of HIV disease. The use of appropriate research instruments for information collection and analysis, such as relational databases, allows for the conduct of large studies, domestically and internationally, with previously unattainable levels of precision and overall quality. In addition, cohort studies offer an opportunity for generating and testing new hypotheses on the pathogenesis of HIV/AIDS and provide biological specimens collected in controlled circumstances and from highly characterized study participants. The availability of specimen repositories from long-term studies will also allow the exploration of toxic effects of drugs and of the variable occurrence of adverse events in genetically varied populations. The assembly of new, representative cohorts, specimen repositories, and integrated databases in developing countries will be important to study key cofactors (e.g., infectious, nutritional, host genetic-related) that modify HIV disease and assess their role in the response of individuals and populations to HIV drug treatments or vaccines. Enabling technologies, including bioinformatics, will be key NIH instruments in increasing the quality of NIH-supported research and the widespread dissemination of its findings.

PRIORITY FOR FUTURE RESEARCH:

- **Implement epidemiologic and simulation studies among HIV-infected individuals and appropriate controls to inform, monitor, and evaluate intervention strategies and to optimize surveillance in domestic and international settings.**

As the HIV/AIDS epidemic spreads to new locales around the world, population-based studies are important to describe the rate of epidemic expansion and the factors that may accelerate or slow its progress. NIH-funded research will continue to conduct epidemiologic investigations and refine simulation studies and surveillance tools, taking into account the variations in the patient, microbial agent, and environment, including discrepancies in health services or provider knowledge. This type of research will inform the design of intervention strategies that are evidence-based, generalizable, and—in the case of resource-poor countries—affordable and sustainable in the face of competing health needs. The global AIDS epidemic makes it crucial to quantitatively assess the impact of interventions—including on risk-taking behavior—particularly when standardized interventions are applied in widely different circumstances. Furthermore, as more intervention approaches are developed and implemented, epidemiologic studies will have to incorporate cost-effectiveness parameters and analyses. This is of particular importance in settings, such as in developing countries, where resources are limited.

PRIORITY FOR FUTURE RESEARCH:

- **Develop and evaluate accurate, reproducible, and affordable virologic, immunologic, pharmacologic, and genetic assays; measures of adherence to therapy; markers of toxicity and comorbidity, and markers of recent infection for use in domestic and international settings; and HIV-related normative parameters for clinical and laboratory settings in resource-limited countries.**

The availability of accurate and reproducible laboratory assays is a critical factor to rapidly acquire knowledge of the HIV epidemic in different populations and geographic areas. Assays are needed to screen populations for virus-related or host-related factors that may affect the diagnosis, prognosis, and treatment of HIV/AIDS. Assays are also needed to monitor HIV treatment toxicities, as the expanding therapeutic armamentarium increases the likelihood of undesired treatment effects. In developing countries, simple and rapid assays are necessary to define the epidemiologic features of emerging or evolving epidemics. As treatment for HIV becomes more widely available in those countries, affordable assays are urgently needed for clinical diagnosis and monitoring, and for

use in hard-to-reach areas. There is a particular need to develop and evaluate assays that are self-contained and have long shelf life under unfavorable environmental conditions.

PRIORITY FOR FUTURE RESEARCH:

- **Characterize the interactions between HIV, host genetics, and the major environmental factors that influence outcomes (viral transmission, response to therapy, comorbidities, and disease progression). This includes how viral genetic variability interacts with the host in the context of different routes of transmission, comorbidities, and host genetic variants or other determinants of the immune response.**

The various aspects of the interaction between host and nonhost (viral, environmental) factors require the exploration of many different elements that might predict or influence specific outcomes. The role of host genetic variation in facilitating or controlling HIV transmission is the object of intense investigation, yet needs to be further explored, especially in populations that have different racial and ethnic makeup. The NIH will support studies investigating the pattern of involvement of host genetic polymorphisms and their effects on HIV transmission and disease progression. Studies are needed to determine the effect of concomitant infections on immunogenicity and efficacy of HIV vaccine candidates. Studies are also needed to identify natural determinants of ARV drug resistance that might compound resistance driven by drug exposure. Finally, factors other than host and virus and their interaction need to be investigated. The expansion of epidemiologic research at this stage of the AIDS epidemic should include the rigorous evaluation of environmental factors, such as physical and social factors, that might affect HIV-related outcomes.

SCIENTIFIC OBJECTIVES AND STRATEGIES

OBJECTIVE - A:

Characterize the risk factors and mechanisms of HIV transmission in domestic and international populations to guide prevention and treatment strategies.

STRATEGIES:

- Identify, establish, and maintain cohorts in which HIV transmission and acquisition can be assessed, including incident cohorts.
- Conduct studies on the molecular epidemiology and the effects on HIV transmission of infection with different HIV subtypes, ARV-resistant viruses, multiple subtypes, and recombinant viruses.
- Evaluate sexual and blood-borne HIV transmission and acquisition in relation to the following:
  - Viral factors such as viral quantity (measures of viral RNA and other quantification methods) in various body compartments (e.g., blood, saliva, and mucosal compartments), viral diversity (intrapatient diversity), and HIV genotype, including subtypes, recombinants, resistance mutants, and dual virus infections;
  - Host factors such as age, sex, hormonal status, strength and breadth of immune response, mental health, patterns of alcohol and drug use, and host genetic factors;
  - Modifiable host factors such as nutritional status; drug, alcohol, and tobacco use; use of exogenous hormones; other infections, including oral infections; other causes of mucosal pathology, including sexually transmitted diseases (STDs); and circadian rhythm;
  - Persistent exposure to HIV (e.g., in HIV-discordant couples);
  - Use of microbicides and barrier devices;
  - Social, cultural, behavioral, and ecologic factors, including such demographic characteristics as socioeconomic status, race, ethnicity, gender, culture, community, and geographic location (e.g., rural, urban, suburban);

  - Sexual activity, choice of partner, duration of partnership, control of STDs, hygienic practices, contraception choices, and cultural practices such as use of traditional vaginal preparations, female genital mutilation, and male circumcision; and
  - Extent to which environmental and other macro-level factors such as war, migration, drug trafficking patterns, political will, and disasters influence vulnerability, risk behaviors, acquisition, and access to care in developed and developing countries.

- Conduct studies (including community-based studies) to understand and quantify the effect on HIV transmission and HIV incidence of widespread use of ART by eligible individuals.
- Conduct community-based studies that assess the impact of community mobilization on treatment success.
- Study and quantify the impact on HIV transmission of medication adherence and related factors such as therapy and regimen characteristics, drug characteristics, and symptom management.
- Study the impact of widespread ART availability and resulting viral load suppression on patterns of risk behavior.
- Conduct epidemiological studies to assess whether the prevalence or incidence of comorbidities such as tuberculosis (TB), malaria, human papillomavirus (HPV) infection, hepatitis C (HCV), Kaposi's sarcoma herpesvirus (KSHV), STDs, or other infections may serve as a predictor of future HIV epidemics.
- Conduct studies that concurrently address HIV and other coinfections such as TB, HPV, HCV, KSHV, and others, by incorporating such research within existing programs of research on HIV/AIDS (e.g., MTCT).
- Evaluate the impact on HIV transmission and disease progression of hormonal contraceptives and replacement therapies, composition of such therapies, pharmacokinetics, and duration of action of repository-form contraceptives.
- Employ epidemiological techniques to evaluate and quantify the impact of different intervention strategies on HIV transmission and prevention.

- Evaluate risks, benefits, and cost-effectiveness of providing prophylaxis against HIV infection after occupational and parenteral exposures to HIV.
- Examine the effects of vaccine trials on HIV transmission characteristics, including the effects on the alteration of transmission by vaccine-induced immunity. Examine the clinical course and markers of infectiousness among vaccine trial participants with breakthrough HIV infection to determine the vaccine's effect on viral load, rates of progression, and on population HIV incidence.
- Conduct studies on medication-assisted substance abuse treatment modalities and access to service (e.g., methadone maintenance, buprenorphine/naloxone, naltrexone, antabuse, acamprosate, and stimulant abuse therapy), alone or in combination with mental health and/or behavioral interventions as HIV prevention interventions, and examine their effects on disease progression and on acceptance of care and treatment.
- Identify effective individual, network, and community-level interventions and determine the coverage needed to decrease HIV incidence in developing and developed countries.
- Further define the timing, mechanisms, and risk factors in perinatal and postnatal transmission, including treatment of the mother, infant feeding modalities, physiology of lactation, long-term effects of perinatal interventions, maternal and infant genetic variation, and kinetics of viral resistance.
    - Assess the impact of breastfeeding practices on MTCT of HIV and on the health of children and mothers.
    - Define how the physiology of lactation impacts on HIV transmission.
    - Assess the impact of maternal ARV regimens of different potency and duration on MTCT of HIV and on the short- and long-term health of women eligible for ART.
    - Study the safety and effectiveness of low-cost, sustainable approaches to prevention of MTCT of HIV, including exclusive breastfeeding in the first months of life with rapid weaning.
    - Determine the long-term effects on mothers and their children of measures to prevent perinatal infection.

- Assess the impact of perinatal treatment and prophylaxis regimens on emergence of ARV drug resistance in the mother and in those infants who become infected despite prophylaxis.
- Assess the impact of maternal ART on transmission during pregnancy and lactation.
- Assess the impact of perinatal treatment and prophylaxis regimens on community-wide HIV resistance to ARVs.
- Determine the impact of ARV resistance on perinatal transmission and pediatric infection.

OBJECTIVE - B:

Use epidemiological research in domestic and international settings to identify the influence of therapeutics and other biological (e.g., coinfections) and behavioral (e.g., access) factors on HIV progression, as shown by virologic, immunologic, and clinical outcomes.

STRATEGIES:

- Investigate the contribution of innate host characteristics to viral measures, immune function, disease progression, and mechanisms for these effects (including host genetic factors and their modulators, sex, race, and age).
- Evaluate the effects of modifiable host characteristics on viral measures, immune function, disease progression, and mechanisms for these effects.
- Investigate the effect on disease progression of viral factors, including viral genotype, phenotype, fitness, and acquired drug resistance to ARV drugs.
- Evaluate the impact of treatment of alcohol abuse, drug abuse, and mental health disorders on the effectiveness of ART, including in the context of specific forms of drug use.
- Identify the individual, provider, and infrastructure factors associated with initiating, continuing, adhering to, and discontinuing ART, and evaluate the impact of these factors on therapeutic outcomes.
- Characterize the changing spectrum of clinical outcomes (morbidity and mortality), including causes of death associated with evolving therapeutic strategies.
- Determine the global patterns of viral resistance (innate and acquired) to ART and how these patterns could influence the long-term effectiveness of these therapies.
- Evaluate the rate of HIV disease progression in conjunction with the effects of feasible interventions (ARV and other prophylactic) in international settings and in populations with different HIV subtypes and variable cofactors such as nutrition and opportunistic infections (OIs).

- Develop new cohorts and maintain long-term followup of existing cohorts, including observational cohorts and intervention populations, to determine the changing spectrum of HIV disease and evaluate interventions, including indigenous approaches, especially in minority populations and developing countries.
- Continue to characterize the epidemiology of HIV/AIDS infection among those who have minimal exposure to ART, those who have virologic and/or immunologic responses to these therapies, and those who have failed these therapies.
- Evaluate the long-term complications of ART on exposed, HIV-uninfected children.
- Examine the effect of the health status of HIV-infected mothers and of ART during pregnancy and lactation on survival of their children, both HIV-infected and uninfected.
- Identify the effects of long-term exposure to HIV therapies on other infectious diseases; malignancies and associated oncogenic infections; cardiovascular disease; and other HIV-associated diseases, including central and peripheral nervous system conditions, oral and mucosal lesions, wasting and other metabolic disorders, and renal, hepatic, bone, and endocrine complications.
- Elucidate the pathogenic mechanisms mediating HIV disease progression in well-defined population subgroups, including the factors that influence residual HIV replication in ART recipients.
- Investigate how different patterns of access, adherence, and exposure to drug regimens in treatment-experienced and treatment-inexperienced populations contribute to HIV drug resistance and disease progression.
- Assess the effect of HIV on other infections (e.g., hepatitis B [HBV], HCV, hepatitis GB virus C [GBV-C], other blood-borne infections, HPV, KSHV, TB, and malaria and other parasitic diseases) and the effect of these infections and their treatment on HIV outcomes.
- Encourage natural history studies that address both HIV and HCV infections and incorporate research on HCV infection within existing programs of research on HIV/AIDS.

- Study HIV-infected children and adolescents to determine factors related to impaired growth and neurodevelopment, impact of other childhood infectious diseases, safety and efficacy of immunizations, and how these may be affected by medical and behavioral interventions.
- Study the effect of HIV infection and its treatment in aging populations with coexisting morbidities and polypharmacy.
- Study the emergence and reemergence of infectious diseases and the development of antimicrobial-resistant infections (e.g., multidrug-resistant TB, sulfa-resistant malaria, antibiotic-resistant pneumococcus, cotrimoxazole-resistant *Pneumocystis carinii* pneumonia [PCP], and lamivudine-resistant HBV) in HIV-infected populations.
- Study determinants of adherence to ART and adverse events of such therapies in domestic and international settings, and in all age groups.

OBJECTIVE - C:

Develop and evaluate methods and resources for epidemiological and clinical studies that use culturally appropriate approaches; incorporate new laboratory, sampling, and statistical methods and information systems; and better integrate research findings into clinical practice and regional, national, and international policy.

STRATEGIES:

- Evaluate and promote the use of study designs that incorporate appropriate ethical, cultural, and policy context for studies in diverse domestic and international populations.
- Support training and mentorship of medical and health professionals in developing countries in the areas of research ethics, study design, data management and analysis, and linking research trials to clinical care, and clinical care to health policy and implementation.

Strategies Related to Natural History/Pathogenesis

- Develop and evaluate accurate, reproducible, and inexpensive virologic, immunologic, bacteriologic, pharmacologic, and genetic assays suitable for large-scale epidemiological research and surveillance in developing nations. Emphasis should be on simple and reliable staging of disease progression for the initiation and monitoring of HIV therapy and OI prophylaxis; HIV resistance testing; and noninvasive diagnostic assays for STDs, other OIs including TB, and AIDS-related malignancies.
- Develop, evaluate, and validate diagnostic assays for rapid HIV detection for both chronic and primary HIV infection, including detuned assays (used to detect recent infection) and assays useful in conjunction with interventions to reduce MTCT.
- Develop new epidemiological designs and statistical methods, including development of informatics tools, to better characterize transmission dynamics and monitor long-term trends in disease progression in the setting of potent ART.
- Develop, maintain, and effectively cultivate ongoing and newly developed cohort studies, domestic or international specimen repositories, and databases for interdisciplinary HIV-related studies. Nested studies that utilize these resources should be particularly encouraged and developed.

- Use observational data to better characterize the natural history of OIs in international settings and trends in the epidemiology of these conditions.
- Develop methods for assessing HIV-related quality of life that are feasible and culturally appropriate.
- Develop uniform assessment tools to measure host and environmental characteristics, including substance abuse and mental health, which may impact immediate and long-term HIV-related health outcomes.

Strategies Related to Interventions

- Study the various operational strategies that can be employed to "bring to scale" ART programs, including the use of operations research and integrated databases to evaluate treatment effectiveness at the individual and population levels.
- Assess the effectiveness and comparability of clinical versus laboratory monitoring for the initiation, monitoring, and switching of ART, particularly in resource-poor settings.
- Develop appropriate clinical and laboratory definitions of short-term and long-term ARV failure.
- Evaluate the impact of continued ART after the failure of multiple regimens.
- For prevention studies in both domestic and international settings, improve approaches for recruitment and retention of populations now underrepresented in such studies, including minorities, children, adolescents, women, drug and alcohol abusers, incarcerated populations, and persons living with mental illness.
- Study the impact of access to ART and vaccines on risk behaviors and HIV acquisition among at-risk populations.
- Develop, evaluate, and promote new, improved, and cost-effective methods to prevent HIV transmission via blood transfusion, medical treatments, and other iatrogenic exposures in developing countries, including instrument sterilization.
- Assess the impact of different strategies for HIV testing and their linkage to care.

- Study the impact of different strategies on morbidity and mortality of the community at large, including non-HIV-infected individuals (e.g., survival of uninfected infants).
- Develop simulation strategies (modeling) of the impact of interventions on HIV transmission, cofactors of HIV infection, and community-wide morbidity and mortality.

Strategies Related to Policy

- Evaluate the long-term clinical impact of different strategies for care, including OI prophylaxis and ART.
- Assess the impact and cost-effectiveness of different aspects of HIV clinical care from an individual and societal perspective.
- Develop methods for disseminating research, making research results more accessible, and linking research results to regional and national standards of care, including formal HIV best practice guidelines.
- Develop formal methods to assess the applicability and transportability of guidelines for care across countries.
- Support HIV policy research, including economic impact studies, necessary for translating epidemiological and clinical studies into policy.
- Identify the effects on HIV transmission and treatment access of changes in drug enforcement policies and activities in domestic and international settings.

FY 2006 OAR Natural History and Epidemiology Planning Group

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